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188

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,722	09/30/2003	Alexander John Walacavage		6356

7590 06/10/2005

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EXAMINER

VANIK, DAVID L

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/675,722

Applicant(s)

WALACAVAGE ET AL.

Examiner

David L. Vanik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Receipt is acknowledged of the applicant's Oath or declaration filed on 9/30/2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 is drawn to an a polymer dressing "dominantly comprised of the amylase form of the molecule." The term "molecule" is absent from the instant specification. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "molecule" and requires further clarification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "optimally controlled" in claim 3 is a relative term which renders the claim indefinite. The term "optimally controlled" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. As such, claim 3 is rejected for being indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,009,648 ('648).

'648 disclose a biodegradable composite film that can be used as a wound dressing (abstract and column 4, lines 3-5). The composition advanced by '648 comprises a starch polymer and numerous biomolecules can be incorporated in the biodegradable film (column 4, lines 6-47). Like the instant application, the wound dressing set forth by '648 comprises cornstarch and can be co-polymerized with

Art Unit: 1615

polyethylene (column 4, lines 6-17). It should be noted that the mode of administration of the composition is considered to be a future intended use and, as such, is given no patentable weight.

The claims are therefore anticipated by US Patent 5,009,648 ('648).

Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,741,521 ('521).

'521 disclose a biodegradable matrix composition (abstract). An active agent can be incorporated into the composition (column 2, lines 2-6). According to '521, the composition is a starch-based material and comprises a high amylase content (column 2, lines 41-65). It should be noted that the mode of administration of the composition is considered to be a future intended use and, as such, is given no patentable weight.

The claims are therefore anticipated by US Patent 5,741,521 ('521).

Claims 1, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,534,561 ('561).

'561 disclose an adhesive composition suitable for wound dressing (abstract). The composition can comprise a biodegradable starch polymer, starch-acrylonitrile graft copolymer, and can be impregnated with a pharmaceutical agent (abstract and column

Art Unit: 1615

4, lines 31-39). It should be noted that the mode of administration of the composition is considered to be a future intended use and, as such, is given no patentable weight.

The claims are therefore anticipated by US Patent 5,534,561 ('561).

Claims 1, 4, 5 are rejected under 35 U.S.C. 102(a) as being anticipated by US 2002/0122771 A1 ('771).

'771 disclose a biodegradable spray hydrogel wound dressing (abstract and paragraph 0025). The wound dressing may comprise active agents, such as antibiotics and diagnostic agents (paragraph 0057). The composition advanced by '771 may also comprise starch and can be fashioned as a hydrogel (paragraph 0070 and abstract).

The claims are therefore anticipated by US 2002/0122771 A1 ('771).

Correspondence

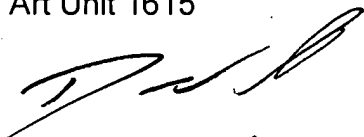

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615


6/7/05
CARLOS A. AZPURU
PRIMARY EXAMINER
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